Section 4: 510(k) SUMMARY

Device Trade Name: Acumed Wrist Spanning Plate

Date: June 14, 2013

Sponsor: Acumed, LLC
5885 NW Cornelius Pass Road
Hillsboro, OR 97124
Phone: (503) 627-9957
Fax: (503) 520-9618

SEP 05 2013

Contact Person: Nathan Wolf, Regulatory Specialist

Manufacturer: Acumed, LLC
5885 NW Cornelius Pass Road
Hillsboro, OR 97124
Phone: (503) 207 1502
Fax: (503) 520-9618

Common Name: Plate, Fixation, Bone
Device Classification: Class II
Classification Name: Plate, Fixation, Bone
Regulation: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories

Device Regulation Panel: Orthopedic

Device Product Code: HRS

Device Description:
The Acumed Wrist Spanning Plate comprises two anatomically designed dorsal fixation plate and is provided in sterile packaging.

Intended Use:
The Acumed Wrist Spanning Plate is intended for fixation of fractures, osteotomies, and non-unions of the radius.

Indications For Use:
The Acumed Wrist Spanning Plate is indicated for fixation of fractures, osteotomies, and non-unions of the radius.

Materials:
The Acumed Wrist Spanning Plate is manufactured from titanium alloy (Ti-6Al-4V) as described in ASTM F136.

Technological Characteristics:
There are no technological characteristics that raise new issues of safety or effectiveness.

Assessment of performance data:
The bending strength performance of the Acumed Wrist Spanning Plate was verified to be statistically equivalent to that of the predicate device. A summary of the objective, acceptance criteria, results, and conclusions, as well as the detailed test reports can be found in Section 36.

Legally Marketed Predicate Device:
Synthes 3.5mm Locking Compression Plate standard bone plate (K082807)

Predicate Indications for Use:
The Synthes 3.5 mm Locking Compression Plate (LCP) System is indicated for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olectranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone for adult patients.

Based upon the similarities of the Acumed Wrist Spanning Plate and the predicate devices studied, the safety and effectiveness of the Acumed Wrist Spanning Plate is substantially equivalent to the predicate devices referenced.

Purpose:
The purpose of this Traditional 510(k) submission is to gain clearance for the Acumed Wrist Spanning Plate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Nathan Wolf
Regulatory Specialist
Acumed, LLC
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124

September 5, 2013

Re: K131764
Trade/Device Name: Acumed Wrist Spanning Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: June 14, 2013
Received: June 17, 2013

Dear Mr. Wolf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3: INDICATIONS FOR USE

510(k) Number (if known): K131764

Device Name: Acumed Wrist Spanning Plate

Indications for Use:

The Acumed Wrist Spanning Plate is indicated for fixation of fractures, osteotomies, and non-unions of the radius.

Prescription Use X AND/OR Over-the-Counter Use

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Elizabeth L. Frank -S